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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/887,028      | 06/25/2001  | Niva Shapira         | 01/22156            | 8373             |

7590 03/22/2005  
Browdy and Neimark  
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Washington, DC 20001

|                     |              |
|---------------------|--------------|
| EXAMINER            |              |
| WEINSTEIN, STEVEN L |              |
| ART UNIT            | PAPER NUMBER |
| 1761                |              |

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/887,028

Applicant(s)

SHAPIRA, NIVA

Examiner

Steven L. Weinstein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15 & 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admission of the prior art in view of Stehlin (FDA Consumer 6/96), Kavanagh (Ford Ingrid. 11/95), Uhle (Milchwissen Schaft 1974) and Zubkova et al (Int'l. Dairy Congress, 1974), and Gurr (Lipid Technology (9(1), 14-17, 1997), further in view of Gunther (Proceedings of the Nutrition Soc., Vol. 38(3), page 113a, 1979), Woolridge et al (Lancet, Vol. 2, pages 382-384, 1988), Wilson-Clay (Mothering, No. 59, page 80, Spring 1991) and Woolridge et al (Lancet, Vol. ii, pages 1292-1294, 1980) or Woolridge et al (1980) is also used as the primary reference in view of applicants' admission of the prior art and all of the above secondary reference evidence.

Applicants' admission of the prior discloses it was known in the prior art to produce formula that comes "as close as possible to breast-feeding"(page 2, paragraph 1 of spec.). Applicants' admission of the art also teaches it was well known in the art that during breast feeding, the infant first receives or is fed a milk called fore milk which is lower in fat content than a second, later portion of milk that is known as hind milk. Claim 1 differs from applicants' admission of the prior art in that an infant is fed two formulas; one that is lower in fat than the other and wherein both formulas mimic in some constituent, which in most claims is fat. It is noted that the specification only defines fore and hind equivalents as being similar or compatible at least in their fat content and/or other ingredients to human fore and hind milk. Thus, claim 1,

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which does not positively recite fat, is readable on other ingredients, not necessarily fat.

Similarly, claim 1 does not state which formula is fed first. Claim 1 only recites they are applied sequentially. Similarly for claim 16. In any case, since applicant discloses that the art tries to match as close as possible breast feeding and since Stehlin, Kavanagh, Uhle, Zubkova and Gurr are all relied on as further evidence that it was well established to provide infant formulas which simulate, copy, reproduce or imitate human breast milk, and since Gunther and Woolridge et al and especially Wilson-Clay teach advantages for the infant to ingest lower fat, then higher fat milk, and since, as evidenced by Woolridge et al (Lancet 1980), applicant is not even the first to feed infants from bottles, modified milk (albeit breast milk) that mimics the fore and hind milk fat contents, to modify applicants' admission of the prior art and feed an infant two portions of formula that mimic fore and hind breast milk for its art recognized and applicants' intended function is seen to have been obvious. That is, applicants' goal is to mimic breast-feeding as much as possible. Applicant admits formulas are known to mimic breast milk as close as possible and it is known that the milk ingested by the infant changes in composition (specifically fat content) during feeding. To provide the infant with a feeding of two portions of varying content that further mimics the known breast milk feeding would therefore have been obvious, especially since there are apparent advantages therefrom, recognized by the art. It is noted that the specification puts forward no advantages/unexpected result derived from feeding a fore and hind milk equivalent formula other than this is what the infant ingests naturally during breast feeding. The overwhelming evidence in the art taken as a whole teaches one to mimic as close as possible the breast feeding experience in formula and one of ordinary skill in the art would be

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fairly led to employ two formulas that vary in concentration of a constituent, and particularly fat, to truly mimic breast feeding which introduces into the infant fore milk and then hind milk.

Employing Woolridge et al (Lancet-1980) as the primary reference, claim 1 differs from Woolridge et al in that the fore and hind milk is formula type milk. Note, however, that Woolridge et al does not use breast milk directly. Woolridge et al takes the breast milk and filters the fat and then produces a modified breast milk that mimics the breast milk that the infant experiences during breast feeding. That is, Woolridge et al feeds the infant processed milk that mimics fore and hind milk. Thus, applicant is not the first to feed infants processed milk simulating the breast-feeding process. The preponderance of the evidence set forth in the art taken as a whole as discussed above teaches that it was well established in the art to mimic breast feeding and the constituents of the breast milk as much as possible and that there are benefits to this natural sequence and to modify Woolridge et al and employ formula that mimics the fore and hind milk rather than processed milk, if Woolridge et al had no adverse feelings toward formula, would have been obvious. The fact that Woolridge et al saw no difference in the sucking pattern or milk intake in one sequence or the other (I.e. low then high or vice versa) is irrelevant. The fact is, the natural breast-feeding pattern is taught by the art and even has advantages so that employing two formulas in the same sequence would more closely mimic breast-feeding, which is what the art desires. Thus, contrary to what has been urged in the last amendment, Woolridge et al does not teach away from applicants' invention. It is again noted that Woolridge et al were only investigating sucking patterns and milk intake and not any physiological result derived from the sequence. It is again pointed out that applicant has not

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offered any unexpected result from mimicking in a formula ingest process what the infant experiences naturally in breast-feeding.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-6 and 15 above, and further in view of Simmons (5,611,776) for the reasons given in the Office actions mailed October 27, 2003 and 6/17/04. It is noted that in the Office action mailed 10/27/03, a typographical error occurred in that although the statement of the rejection rightly cited Simmons et al, the body of the rejection incorrectly employed the name Vinciguerra, from a perusal of the references, Simmons et al obviously is the reference which employs two compartments; Vinciguerra does not.

All of applicants' remarks filed December 16, 2004 have been fully and carefully considered but are not found to be convincing. The remarks are found to either be moot in view of the new rejection or are addressed above in the body of the rejection.

Any inquiry concerning this communication from the examiner should be directed to Steven L. Weinstein whose telephone number is (571) 272-1410. The examiner can generally be reached on Monday-Friday from 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S.L. Weinstein/dh  
March 7, 2005

*Steve Weinstein*  
STEVE WEINSTEIN  
PRIMARY EXAMINER 1761